Episode 42 – What to do about drug shortages

Intro music: 0:00

Podcast introduction: 0:10
A few months ago, I received multiple telephone calls within the span of a few days, all seeking advice on how to find insulin. Although the circumstances in each case were different, the basic problem was the same: insulin is in short supply, and the patients had been unable to fill prescriptions for it, despite checking with multiple pharmacies. This is Jean Fisher Brinkley, Communications Director for the North Carolina Medical Board, and this is MedBoard Matters. For the record, the medical board probably isn't the best resource for patients with concerns about drug shortages. The medical board has no authority over the manufacture of prescription drugs and, as such, has little insight into supply issues. And to be honest, I had no idea what to tell these callers. But the questions piqued my interest and, as a recovering newspaper reporter, I could not help trying to find some answers. Why do shortages of insulin and many other prescription drugs occur? What should people who can't fill prescriptions because of a shortage do? And can prescribers do anything to help patients dealing with medication shortage? I asked Jay Campbell, a pharmacist and attorney who serves as Executive Director of the North Carolina Board of Pharmacy, to talk me through these questions and more.

Interview with Jay Campbell: 1:34
JFB: Jay, thank you so much for joining me. It's great to have you on MedBoard Matters.

JC: Hey, Jean, thanks so much for the invitation. It's great to be here.

JFB: You have not been on the podcast before. Would you introduce yourself to our listeners?

JC: Sure. So, I'm the Executive Director of the Board of Pharmacy, and I've been here at the Board of Pharmacy since 2006. My background is I'm a graduate of the UNC School of Pharmacy, and I practice mostly as a pharmaceutical researcher for about a year and then went to law school at Vanderbilt University. And after I finished law school, I was a judicial clerk for a year and an appellate litigator for almost nine years, and then came to the Board in 2006 and somehow have managed to hang on for 18 years.

JFB: Wow. Well, that is an interesting path back to pharmacy. I'm curious, you know how you happened to take such a long detour from the world of pharmacy before finding your way back?

JC: It would be a lie to say that any of it was planned, that's for sure. I actually originally Jean was going to go into a PhD program in pharmaceutics, and the year after I graduated from pharmacy school, I worked as a researcher at Glaxo in the field while I was getting my feet back underneath me and, getting ready to move on to the next thing. And...and honestly, Jean, I just I wasn't a great bench scientist, and so I figured out pretty quickly that was not a path for me, or at least was not a path that any PhD advisor would enjoy having me on. So, I had always had some interest in law, that stem back to some things I had done as an undergrad that I did not that were done to me by the law. I should be clear about that. And, so when I'm going to law school and when I went to law school, I had some vague notion that maybe I'd try to combine the pharmacy background with law, but it just the way things worked out, I fell into litigation, and I was an appellate litigator for most of that time. And that was really fun and

interesting and, and high stakes work to do. But the way I came back was, I practiced in DC for several years and had moved back to North Carolina and was practicing law in Charlotte and started teaching the pharmacy law class at Wingate University, which had opened a pharmacy school when I was living in in DC. And one thing led to another with that, I, by teaching that law course, I got plugged back in with my predecessor here at the pharmacy board, David Work, who taught me pharmacy law, and he called me one day and said, it's not public yet, but I'm going to retire and the Board is going to do a search but I think you should be a candidate. So, I put my hat in the ring and wound up here. But like I say, every bit of my being here is just some happy intersections of different things. But it's been rewarding. I will be honest, Jean, when I started here, I didn't know that it would turn into my life's work, but it has, and it's been enjoyable, and I think I've got at least a few productive years still in front of me.

JFB: Well, thank you for sharing that. And I would imagine that it's never a bad idea to have a good understanding of the law, no matter what field you're in, so I can certainly see there would be some synergy there with the work that you're doing.

JC: By statute, the Executive Director of the Board of Pharmacy has to be a pharmacist. So, but yes, Jean, you're absolutely right. This job, as you well know, by having the law background is critical, I think.

JFB: Yeah, the reason that I had invited you to be on the podcast arose because I got a series of phone calls from patients in North Carolina who were having difficulty accessing their medication. Specifically, it was insulin. So, I had this series of calls. It was three, maybe four calls where people were saying, I'm a diabetic, I'm on insulin and I can't find it anywhere. What should I do? And I was really stumped because this is a little outside of the issues that we normally work in and the questions that I normally answer. So, I did not know what to tell them. And I thought, you know, I was a little shocked by the issue because I was like, insulin is a pretty darn important drug to have. It's not like they can just go without it. And I thought, I need to know, you know, how to answer those questions if we get them in future. And I thought our listeners, you know, patients who perhaps listen to the podcast and our licenses would both benefit from having more information about drug shortages, how they arise and what, if anything, you can do, you know, if you find yourself unable to access your medication. So, I'll just start by asking you, can you explain why do drug shortages occur?

JC: You're right. There's a lot more of it in recent years. And I get the same calls that you do. And so, I look forward to talking about some strategies that both patients and prescribers can employ to at least mitigate the issues. But there aren't any magic bullets. But to answer the question you're asked, there are always some drugs that are going to be in shortage. And historically, drug shortages were attributed to here might be some particular problem at a manufacturing facility, which is not a great situation to be in. But the advantage to that, if that's the right way to describe it, was you could point exactly to what the cause of the shortage was. And because you could do that, it was relatively easy to get a fairly accurate prediction of how long the shortage was going to last and how it's going to be resolved. And that was certainly true for the kinds of medications that patients take for chronic disease management and other things. A lot of shortages historically have also been for IV drug products that are administered, particularly in hospital facilities. So generally, the same issue that there is some particular problem on a manufacturing line. And it's you can point at that, and the FDA knows what's going on, you can fix it. But the sheer number of drugs that have been on shortage, it seems to increase every year.

And some of that is due to manufacturing issues. Sometimes, frankly, Jean, they're due to market issues. That's not so much the case for drugs that patients take for chronic disease management, but that can and sometimes is a problem with some IV preparation products and the like, where some manufacturers may look at that and say, you know, economically this I don't think this is the best use of my facility. So, there are various reasons why it comes up. With at least one class of drugs that's been in sort of perpetual shortage for the past year, it's not a problem with production. it's not a problem with economics, it's just an issue that demand for those drugs so far outstrips the capacity of the manufacturers. Even operating manufacturing plants full speed 24/7 simply can't keep up with the demand. So, there's not one single factor involved here.

JFB: Right. That makes sense. Yeah. Okay. Well, I mentioned insulin and I would love to get your insights on what's going on with that drug in particular. But could you give an example of a drug where the demand for it outstrips the supply?

JC: Yeah. What are called the GLP-1 drug, Semaglutide, yes. That is the big one. The drugs that were developed principally to manage type two diabetes but also obviously have significant use in weight loss. And of course, that has made those drugs incredibly popular. And the manufacturers, again, don't have don't have a problem with plants or down or they can't get the active pharmaceutical ingredient to turn it into a finished product, it's just they simply cannot keep up with demand.

JFB: Yes, that certainly tracks. You can't open a newspaper or magazine blog without reading something about the GLP-1. And yeah, and not just for weight loss anymore, right? That they apparently have all kinds of applications.

JC: So yeah, the research of that as to the potential uses seems almost boundless at this point. But you're right. I mean, imagine if you're a diabetic who absolutely needs these drugs to manage your diabetes and you can't get it because where that's being pushed to weight loss use, which I'm not saying that's anything clinically inappropriate with that, but you can imagine that if I were a type two diabetic, I would be very concerned about that.

JFB: Now, can you explain a little bit more about what specifically is happening with insulin shortage?

JC: I don't have a great insight on to insulin shortage. I mean, insulin, obviously, biotechnology product, at least the human analogs for insulin and that those are, again, I couldn't get down to the fine weeds, and the cost, but those are manufacturing issues. They're complicated manufacturing processes. And, you know, if something goes wrong or there's a hiccup in a manufacturing process, it's not a quick thing to recover from when you're talking about a bio engineered and biotechnology produced product.

JFB: Okay. So, I guess long story short, it's multifactorial.

JC: Yeah, it absolutely is. Which is…which is no comfort to patients' prescribers, but it is multifactorial.

JFB: Okay. So, lots of reasons. So, let's say you're a patient. You go to the pharmacy, they tell you no we don't have that, and we can't get that drug, so we can't fill your prescription. What options does a patient have if they're in that situation?

JC: Yeah, it's tough and there's no perfect answer to any of this. But the first thing I'd start with, Jean is sort of reminding folks of the importance, especially if you're managing a chronic disease state, the importance of having an established and ongoing relationship with a pharmacy or a pharmacist. I am not, of course, remotely unaware or insensitive to issues about drug price and cost and access and those sorts of things. So, I well understand and am not critical in any way of folks that may need to use different pharmacies for economic reasons. But if you have a chronic disease and it's being managed, you do yourself a big favor for having an established relationship with a pharmacy, with someone or a few people at that pharmacy who are familiar with you are familiar with your health history, probably have an ongoing knowledge and relationship with physicians and NPs and PAs that are treating you so that the lines of communication are open and -

JFB: I was going to ask you to say why that would be so helpful. How does it help you?

JC: So yeah, it's one, yeah. It's one is just a line of communication and understanding of what your needs as a patient are going to be, and also provides an opportunity for more proactive measures. If, you know, the pharmacist realizes is there is a shortage in this drug and I've got 40 patients that are being treated for this chronic disease and are on this particular drug, it's very helpful for that pharmacist to know that, it can help them husband their resources when it comes to those drugs. It also very much helps facilitate any needed conversations with treating physicians or other health care providers about alternatives in life. So, I think that's and look, obviously that's…that's nothing unique to pharmacy. It's the same reason it's always you should have a primary care provider that you have a relationship with for all the same reasons. So, I think one is put yourself in a position where there's the highest chance of someone understanding your situation and being in a position to sort of proactively help you with that. Now, that's not always going to solve the problem, but it helps to be able to talk to somebody who understands your situation.

JFB: So, at the pharmacy counter just be saying, okay, what do you recommend? Can the pharmacist help you? Or should you go back to, you know, the front desk?

JC: Yes, certainly the pharmacist can help you. I mean, if you if you're facing a really severe shortage. Now, of course, one thing a pharmacy can do, and they often will do or say, you know, I'll check around with some other pharmacies and see if anybody has that drug in inventory. They might also be able to check with their wholesaler or to provide the patient with such as say, look, I don't have it today, but I just checked with the wholesaler. We're expecting it tomorrow or whenever it's going to happen. So, you can certainly look for other sources to get the drug. And, you know, again, I think if you're you got a well-established relationship with the pharmacy, I think most pharmacies would be more than happy to help you with that. But then the issues do kind of obviously, Jean, about, well, you know, I've got bad news for you. I don't have it. I don't know anybody else who has it. My wholesaler says they don't have it and it's going to be, you know, maybe two weeks before they get it or whatever the case may be. Then you've got to start thinking about alternatives. And certainly, a pharmacist has more than sufficient training and knowledge to say, well, you're on this particular drug, let's say, for the treatment of hypertension, this is your drug that's in shortage, there are alternatives. And part of that certainly could involve, and now the pharmacies can't change that themselves. But it certainly could facilitate the communication with that patient's primary care provider or whoever is prescribing medical therapy for

that disease state and having the conversation about alternatives. Now, obviously, Jeana, that's easier for some types of drugs than others. I mean, if you have a patient who's established on a particular type of insulin, I mean, yes, you can change different insulins, but there's going to be more monitoring involved with that, as you understand and would expect with, you know, some other drugs, it may be less of a disruptive let's say, change to chronic drug therapy. But having those conversations and looking at alternatives, that is absolutely something that a pharmacist can and will work with a patient on. And then especially again going back, if that patient has a home at that pharmacy and a familiarity, then there's very likely that the pharmacist also has a relationship, maybe not a deep relationship, but a relationship with the providers. And that just helps facilitate that communication.

JFB: Okay. Yeah. So, I was going to ask you about some of the challenges. And I think this issue with finding a suitable alternate medication would certainly be high on the list of barriers to be able to work through this. But as you said, there isn't a magic bullet that can fix this. But these are things that you can at least ask about.

JC: Absolutely.

JFB: Okay, so how long do drug shortages typically last? I know it ranges.

JC: Yeah, it's all over the map there. I've seen shortages on FDA's list, they get up and they're resolved, in, you know, a matter of a month or two. And then there are other shortages that persist for years. I mean, again, certain IV fluid, I think most of the folks are listening to this aren't showing up at the pharmacy and saying, oh, I'm here for my monthly bag of, like, data Ringer's solution to infuse. But a lot of times that's an example of a type of product that seems perpetually in short, I'm not talking about lactate or Ringer's specifically, but IV fluids generally, and those shortages never seem to completely resolve. They get better, and then they come back, and they get better, and they come back. But, you know, going back to the GLP-1, they've essentially been in shortage, as the FDA defines it, since they were put on the market. And as far as I can tell, the only way that shortage gets resolved, right, because I certainly don't expect there's going to be a drop in the demand for those drugs, that the only way that shortage gets resolved is, addition of more manufacturing capacity. And that's, shoot. That's you understand, that's not something that happens quickly for any drug product. And now you're talking about a long chain peptide drug. And that's a much more complicated manufacturing process than what are called small molecule drug signs. They can persist for quite some time. And then, you know, occasionally you run into the issue where there's a drug that maybe the brand manufacturer hasn't manufactured it for years because the generic manufacturers moved into the market. And you can run into a situation where their generic manufacturer says this is just not economically viable for us to continue manufacturing this product, and they may get out of the business altogether. That's not super common, but it does happen from time to time. So, they range, Jean, from like say a couple of months to without apparent end.

JFB: Okay. You mentioned the FDA, how does the FDA define drug shortage.

JC: Yeah. And it should have been careful about saying definition is I don't want to sort of wade into a lot of high granular detail about that. But there are certain obligations that manufacturers of drug product have to alert the FDA if they find themselves not capable of meeting the demand. Either because you

know with the GLP-1s that we can't meet the demand because too many people want it, we can't catch up. Or we had a manufacturing line shut down because of technical or other problem. So, they're required to let FDA know about that. And FDA if a drug, well, let's just say a molecule is in short, I it, maybe I shouldn't use that term. But the drug product or the pharmaceutical ingredient itself, if it's in shortage, the FDA will say that drug and all of its forms are considered to be in shortage. But if you go on to the FDA's shortage list, it'll have, you know, sort of at the top line semaglutide, and it'll say it's in shortage. But then below that, the FDA will list each of the dosage forms and dosage amounts of that drug. And sometimes within that, you'll see, okay, even though overall the drugs in shortage, this dose and this dosage form is available, and some others maybe are not. So that is a resource whether you're a pharmacist or you're a primary care provider, that's another place to go look, because when you're thinking about alternatives, it may be possible to keep a patient on the same drug, but maybe a different dosage. Strength is available. So maybe you need to, you know, prescribe it and say, well, you know, you take this fewer times a day or you take half of one if it's a dosage form that's capable of being divided. So sometimes you may not be able to perfectly maintain what someone is on, but there may be an alternative that is the same drug that's just going to involve a little bit of manipulation of the directions or the -

JFB: Gotcha. Well, thank you for mentioning that. That seems like it would probably be one of the more desirable solutions.

JC: Absolutely. And that's a solution that's commonly employed where for some reason, let's say the 15-milligram dosage form of the drug, nobody has it. But the 30-milligram dosage form is available. Usually, you can overcome that.

JFB: Right. Get yourself a pill splitter.

JC: Yeah, exactly. Or ask the pharmacy to do it for you.

JFB: Okay. So, you mentioned drug shortages being resolved. And again, I also don't want to get overly technical, but when is a drug shortage considered to be resolved?

JC: Really the way is, is at such time that the manufacturer reports to the FDA, we are capable of meeting the mean demand that we have for the drug. I mean, the FDA does not, and this is probably something that folks understand, the FDA doesn't have any power to order a manufacturer to make more or less of anything. So, when drugs are in shortage, it's not like the FDA can ring up Pfizer and say, folks can't get their Lipitor or whatever, so we're issuing an administrative order for you to put on an actual shift at the Lipitor or plant. So, it's reliant on the manufacturers keeping FDA informed about their ability to meet the demand. And I don't know exactly what the metric is that the FDA would say, well, we declare the shortage to be over, but it is based on the reporting from the manufacturer.

JFB: I suspect that patients have a different definition.

JC: I'm sure.

JFB: Drug shortage is any as long as you're having difficulty filling your prescription.

JC: Oh, that's right. And that's a great point. That's a great point to raise because sometimes, you know, right. We've been talking I've been talking about what shortage means under the Food, Drug and Cosmetic Act. But you're right. There can be an overall, it could be the case that overall a drug is not in shortage, but you can have distribution challenges and maybe over a given period of time, local wholesalers have less of a particular drug that's not a shortage overall, but the effect to the patient is the same. Fortunately, those tend not to be as long lasting, that if it's just a product distribution among wholesalers that's far more amenable to resolution in a relatively short period of time, then things like, well, our manufacturing plant is not operational.

JFB: Right? Right. Well, I guess that's a bright spot. How serious a problem do you consider drug shortages in the US?

JC: I think it's a serious problem, especially, I shouldn't say especially. I mean, any shortage is a problem if you're a patient who needs to have a cardiac surgical procedure, and that procedure has to be delayed because there is a shortage of X fluid or X anesthetic agent, that's a problem, obviously, but again, sort of shifting, and I think our focus is more to folks who are not in a hospital getting an acute procedure, but managing their chronic health issues. If you can't, I mean, look, if you're a type one diabetic and you if you're insulin, you've got an immediate and urgent problem. But even beyond that, if you have shortages of medications to manage chronic hypertension or chronic dyslipidemia, or any number of disease states which are prevalent in the United States and are contribute to an incredible amount of morbidity and mortality in the United States. And you can't get the drug, I mean, you go without your blood pressure medication for a month, you're at high risk for cardiovascular or cerebrovascular event. So, it's an enormous public health issue.

JFB: And what is being done to address the issue, if anything?

JC: Well, I wish I knew, but certainly I wish I had had the answer to that. I would probably -

JFB: I mean, I know it's difficult because there’s not one clear answer -

JC: There’s not one. Clearly there's not one. And Congress and the FDA, periodically you read about efforts to try, but I think, Jean, that largely the efforts to try to deal with drug shortages are and sort of, by necessity, have to be aimed more at better communication about those and maybe better monitoring of the distribution process to see what can be done about making sure that if a drug is either overall in shortage or there's a distribution that makes it difficult to get in a particular area, that folks are looking to make sure that the drugs are moving around in a way that provides the most people possible with the opportunity to continue drug therapy uninterrupted. The communication part I don't, maybe that's not so difficult about putting things out, assuming that folks pay attention. But again, there's no authority that any governmental agency has to order a particular drug company to make more or less of anything. So, I there's not a great top-down solution. I know that one of the things that is talked about a lot is in the United States, there used to be a far more robust prescription drug manufacturing industry than there is today. There aren't all that many manufacturing plants in the United States anymore. A lot of that is handled in the far East and various other countries. And I'm not saying that to make any political point whatsoever, but there is just a reality that any product that's acutely needed for public

health purposes, and the majority of that is relying on a global manufacturing and distribution mechanism, we just we certainly learn a lot about that during Covid.

JFB: Absolutely, yeah,

JC: That creates problems. And so there has been a lot of talk among policymakers about what incentives should be created to reassure pharmaceutical manufacturing, both finished product and also what is called the API, the active pharmaceutical ingredient or for a lay listener is, you know, the chemical that that is the active part that, reshoring some of that. But again, that's a complicated term.

JFB: Yeah, these are long term, multi-year –

JC: And those long-term solutions, I do think to credit to policymakers, I think a great deal of thought, a very thoughtful consideration of long-term solutions is going on. And again, I think reshoring and…and shoring up the domestic capacity to manufacture these things would help. But that's not going to help a patient today who is having trouble finding their insulin.

JFB: So, I'd like to shift focus, if we could, to the medical professionals who prescribe medications now. And I'll start asking you a similar question, which is how should prescribers prepare themselves to deal with drug shortages?

JC: Yeah, yeah, I think the key I mean, again, one of the keys of our top down is to maintain some familiarity with which drugs are in shortage. Like I say, particularly if your practice involves treating folks for chronic disease states, it doesn't mean going and checking the FDA shortage list every day or whatever, but no one lacks for resources to be able to easily have a sense of here the drugs that are on shortage and the classes of those. So just being aware of that in a general sense, because obviously, if an alternative is needed and is available, I'm sure everybody along the chain finds it a better outcome to have that dealt with at the point of prescribing, right? At least at that point, at the start of it, the prescriber is aware that there's a shortage, there's a problem. They can if they're capable of making a switch, they can do that right then and then that propagates down. And it's probably easier, easier for the patient.

JFB: So, they would maybe not prescribe a certain medication. They might start with something else that's not in shortage.

JC: Yeah. Or even or conceivably even, so I've seen this happen before is writing a prescription that maybe for what the patient has been taking, and then even putting on their prescription that this isn't available.

JFB: Okay, yeah.

JC: I authorized this as a, as a sort of authorizing in the prescription itself. Now, that's still, you know, any prescriber can authorize a pharmacy to substitute a generic drug for the brand drug, but this would be a little bit different. It's saying it could write a prescription that says if X is not available, then I authorize you to dispense the Y to this patient, even if they're not generics.

JFB: Okay. So that's that strategy that the prescribers can use.

JC: They can.

JFB: Is to sort of think ahead and say, hey, I know my patients sometimes have difficulty getting this drug, so let's give them the alternative. And then that saves the need for that phone call, you know.

JC: It does, it does. So that's the pro argument. And look I understand it's hard for anybody to keep up with exactly what's in shortage at any given moment. But a general awareness I think goes a long way. And then so the reactive part, I assure prescribers, a pharmacy has, and a pharmacist is every bit as excited to be having to call you in the middle of a busy day seeing patients to say, we cannot get this antihypertensive medication, it's on shortage. I need you to consider some alternatives. The pharmacist is every bit as excited to have to make that call as the prescriber is to receive the call -

JFB: Which is, not very.

JC: Not very. That's right. Right. Not very. Not because anybody doesn't care or want to take care of the patient. Obviously, everybody's focused in on that. But people are busy. But having some grace and understanding that if a pharmacist is reaching out and making that call, they're trying to help your patient. It's inconvenient for them as well, but sort of having some grace, and that's where I think to Jean, that having at least a general awareness of what kinds of drugs are on shortage helps, because then when that call comes in and maybe there's some of yeah, I know that those drugs are on shortage, then that's probably why this call is coming in. So, I think giving everybody along the chain some grace and patience on that goes an awfully long way.

JFB: Hey, let's talk about transferring prescriptions because we talked earlier about patients hunting around, maybe finding if their regular pharmacy doesn't have a drug, maybe a pharmacy in the neighboring county does. Is that something, you know -

JC: That that is.

JFB: Absolutely.

JC: Yeah, that's a strategy. Of course. That's generally going to be at the pharmacy end of that, right. Because the prescribers issued the prescription, the pharmacies received it, a pharmacist got the ability to search around, they find it somewhere else. Certainly, a pharmacy can transfer the prescription. Now for drugs that aren't controlled substances, and I know you know what I mean by controlled substances, but let's say an opioid or a benzodiazepine, those sorts.

JFB: Oh yeah. Yeah. Stimulant.

JC: Right. That's because that's a big shortage drug in recent years. Transferring a non-controlled substance, again it's you know time that pharmacy has got to put in doing the process. But now that electronic prescribing is really you know that pay for prescriptions and phone prescriptions these days are very much the exception. And receiving an electronic prescription for a non-controlled substance. And then if you have to transfer it, not difficult to do at all. Where there really has been a challenge though, Jean, is with controlled substances. And let’s use the stimulant drugs as the example. So, if Adderall has been on shortage, an often-severe shortage for, gosh, at least a couple of years, and it was the case under the law that the DEA interpreted their rules as prohibiting a pharmacy from transferring

a controlled substance prescription that the pharmacy couldn't fill at all. Now, there's a rule that allows a pharmacy to transfer refills of a controlled substance. But DEA, and I could go on at length about this, I think this was a self-inflicted wound from DEA. It was not an implausible construction of their rules, but maybe not a practical one. But at any rate, DEA said no, get a prescription for a controlled substance and you can't fill it at all. You can't transfer that to another pharmacy. So that created this awful situation where pharmacy's hands were completely tied. And the only way to get that prescription to another pharmacy was you have to call the prescriber, communicate with the prescriber, and say, I need you to send another prescription to this pharmacy because we don't have it. And of course, prescribers, very frustrating to them. I don't understand why can't you transfer it over? The answer was DEA said you couldn't. The DEA did last summer, finally, after six years, after sort of creating this mess, the DEA last summer passed a rule that authorizes the transfer of unfilled controlled substance prescriptions. And of course, that rule came out with great fanfare and great celebration. Thank goodness. Now there's an opportunity. Well, not quite.

JFB: Okay.

JC: The rule did establish an authority to transfer those prescriptions, but the rule itself said that any transfer of an electronic controlled substance prescription that's unfilled had to move from one pharmacy to another pharmacy without any change at all. No change in the electronic fields, no change in the electronic format. You couldn't, for example, convert it to a fax and fax it to another pharmacy and, DEA apparently, I should say believe, there was nothing apparent about it. They said a DEA believed at the time they passed the rule that the technology allowed that sort of electronic transfer. It didn't. DEA had a fundamental lack of understanding about the technology. Now, and flash forward now to August of 2024, and an electronic standard that is capable of making those transfers now has been approved. But it's still going to be, I'm told, by those who know about such things. And Jean, what my IT and scrip standard knowledge is exhausted by saying something like scrip standard that's it. But I am told by those who I am confident have the expertise on this that change is underway. But that's not a quick change that implementing what's called a new script standard into all the various electronic systems, both the e-prescribing systems and then the systems pharmacies used to communicate. That's going to take a while to roll out. I've been told ballpark it about six months before most systems, that it doesn't mean six months from now, magically, everyone's going to have it. But once that happens, I mean, that's going to be a real improvement because, you know, again, going back to the stimulant drugs that have been on shortage, that will at least create a means by which if a patient goes into a pharmacy, pharmacist says got I do not have this. But, you know, I talked to my friend in the next town, they do have it. I can transfer it over; they can transfer it over. And the prescriber doesn't have to get involved. But where we sit still today -

JFB: Controlled substances. Yeah. Are a very special kind of headache.

JC: Yeah. It takes a new prescription and it's frustrating for everybody. I mean I've gotten calls from physicians very, very frustrated, about that. You know, when a patient or the pharmacy says, you know, for the third time they keep going for pharmacy to pharmacy. Let me be clear, I'm not saying they're going from pharmacy to pharmacy for any nefarious reason, they're just trying to find the drug they've been -

JFB: Right.

JC: Prescribed and there's appropriate for them and having to.

JFB: I's a hassle, yeah.

JC: Yeah, very much a hassle. Very much a hassle for everybody concerned. But hope is -

JFB: Yeah, getting better.

JC: Improvements on the way. I am assured by those who understand these sorts of technological things.

JFB: Okay. Now you have mentioned the FDA shortage website a number of times. I was going to ask you sort of what your recommendations are for prescribers who want to inform themselves about current direction.

JC: That would be the place to go if you go to the FDA website, fda.gov and you go in their search function and type shortage list, it will come up and you will have it. Now, you know, and it's searchable. It's easy to search. You can type in even I think you only have to type in three letters of either a drug's brand name or its generic name and can look to see what's on there. But I also, I can't point to individual publications, but there are other resources out there that will have taken that look at the FDA shortage list for you and say, you know, FYI, here are the things that insurers, the American Society of Hospital Pharmacy does that. And I'm sure within different specialties, if you're a primary care provider that treats a lot as any would, a lot of patients with dyslipidemia or hypertension or type two diabetes, etcetera, etcetera. You can find any number of resources readily that will give you at least a 20,000 ft assessment of the market.

JFB: Okay, great. Jay, that is all the questions I have for you. Is there anything you would like to say before we finish our conversation?

JC: No, I except to thank you for giving me the opportunity to talk about it. I've had some version of these conversations with lots of pharmacists and lots of physicians and PAs and NPs over the years, so I'm really grateful for the opportunity to talk about them in a format that may get it out to lots of folks out there, but then coming away again, we all feel the pain at every level from prescriber or to patient. And my experience has been that, as with most things, 99 folks out of 100 are doing their dead level best to deal with a difficult situation and doing that for the most part, with a lot of grace and patience. And that I think is…is welcome and necessary and is going to continue to be necessary for some time.

JFB: Okay. Well, Jay, thank you so much for your time and your expertise. I have learned a lot, and I feel certain that our listeners will learn a lot. And I want to say thank you in advance, because now I know that I can send all of my pharmacy calls directly to you.

JC: Yeah. So, yeah, the only thing is make sure before you send them to me, you make sure that somebody uttering the word prescription doesn't trigger a Pavlovian referral. Sometimes they it's not actually a pharmacy question, but yes. And folks who are listening, they should know the Board of Pharmacy, we, as I know y'all are, Jean, at the Medical Board, we're very direct contact forward. We have a great website. Y'all have a great website to we're constantly updating materials on the website.

We just launched a revised version of our website. We have a lengthy FAQ section that itself can be search by keyword. So, there's lots of good stuff there. But if you got a question call, we'll get you to someone who, if it's possible for us to provide you with the information from here, we'll get you to someone here. We can get it to you.

JFB: Right? I was just teasing, but. Yes.

JC: No, no, no, I know, but it's a real thing we do.

JFB: Exactly. You're exactly right. We do the same thing. We try to anticipate and provide as much information as we can. But there are going to be some situations where people just need to call and talk to a person. And the good news is, is that there are people working at both your Board and my Board who are there to help.

JC: We're lucky that way, Jean. And I hope folks do understand, I think folks who may have practiced in other jurisdictions or lived in other jurisdictions, we are very lucky in North Carolina that the way our Boards are structured and administer really does provide us with the means to be contact forward. And that is not the case in a lot of states, and that's no criticism of those states. You can only do what you can do with the resources that are available to you. But we're very, very fortunate here in North Carolina.

JFB: Well, Jay, thanks again.

JC: Yeah. Thank you, Jean.

Episode closing: 40:13

That brings us to the end of another episode of MedBoard Matters. Unfortunately, there's just no perfect solution to drug shortages, but I hope you still found the information helpful. Learn more on our show page, which you can find at www.ncmedboard.org/podcast. If you have comments, questions, or suggestions for how to cope with medication shortages, shoot them to us at podcast@ncmedboard.org. This is your host, Jean Fisher Brinkley, signing off. Thank you for listening and I hope you will join me again.